

EXHIBIT B

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: BOSTON SCIENTIFIC CORP.,
5 PELVIC REPAIR SYSTEM MDL NO. 2326
6 PRODUCTS LIABILITY LITIGATION

7 THIS DOCUMENT RELATES TO :

8 ROSEANNE SANCHEZ and ROY SANCHEZ,)
9)
10 Plaintiffs,)
11 vs.)
12) 2:12-cv-05762

13 BOSTON SCIENTIFIC CORPORATION,)
14)
15 Defendant.)

16

CAROLYN FRANCIS SMOTHERS,)
17)
18 Plaintiff,)
19 vs.)
20) 2:12-cv-08016

21 BOSTON SCIENTIFIC CORPORATION,)
22)
23 Defendant.)

24

KATHERINE L. HALL,)
Plaintiff,)
vs.)
2:12-cv-08186

BOSTON SCIENTIFIC CORPORATION,)
Defendant.)

VIDEOTAPED DEPOSITION OF
STEPHEN F. BADYLAK, D.V.M., Ph.D., M.D.
January 31, 2014

1 purports to be an Exhibit B. I have the
2 report, which lists in it, just by footnotes,
3 as I've kind of counted through, eight
4 articles. You see --

5 A. Yeah, those are the eight articles
6 specifically referenced in the report itself.

7 Q. Right.

8 A. Correct.

9 Q. Is there, then, an additional list of
10 literature that was supposed to be attached as
11 an Exhibit B?

12 A. There is.

13 MR. PERDUE: We'll make an effort to try
14 to get whatever that is.

15 MS. GROSSMAN: Exhibit B was attached to
16 his report initially.

17 MR. PERDUE: Is it just a list?

18 MS. GROSSMAN: It is.

19 MR. PERDUE: Okay. Well, I -- to make
20 sure you and I are discussing the same thing,
21 we may have to take that up at lunch or
22 something.

23 BY MR. PERDUE:

24 Q. So in addition to the footnotes in the exhibit

1 that is Exhibit 3, your report for all the
2 respective cases, there's then a list of
3 literature that you would identify as -- that
4 serves as a body of medical literature,
5 scientific literature on which you have
6 reviewed and relied in coming up with your
7 opinions in this case?

8 A. That was included. That was part of forming
9 my opinion, you're correct.

10 Q. Okay.

11 MS. GROSSMAN: And, Jim, to be clear,
12 Exhibit B, if you want to look at my copy,
13 doesn't -- isn't limited to clinical and
14 scientific literature. There's some
15 deposition reports and other things referenced
16 here.

17 MR. PERDUE: Okay.

18 MS. GROSSMAN: Do you want to look at
19 this?

20 MR. PERDUE: Yeah. Let me -- do you
21 mind if I have a copy of it --

22 MS. GROSSMAN: No.

23 MR. PERDUE: -- because...

24 BY MR. PERDUE:

1 MS. GROSSMAN: Object to form.

2 A. I guess it depends what they're -- what
3 they're being asked to give an opinion on,
4 so...

5 Q. Did you do your own research into the field of
6 clinical literature on the issue of
7 polypropylene and tissue response in the human
8 body?

9 A. Did I do my own literature review? Is that
10 what you're asking?

11 Q. Yes, sir.

12 A. I certainly did a literature review. The list
13 that you see, though, is a combination of
14 articles that have been provided to me as well
15 as my own.

16 Q. I -- that's probably the question I should
17 have started with because that's kind of what
18 I was assuming, but I came at it with the
19 second question.

20 There's a -- there's a list that's in a
21 table. There's a list that's in a list.
22 You've already told me that the final product
23 here that is Exhibit B was -- was drafted in
24 the end by the attorneys for Boston

1 A. No. That was provided, actually, by counsel.

2 Q. Okay. So the highlighting in this was on the
3 copy that counsel provided you?

4 A. Correct.

5 Q. Is this -- is this an article that you were
6 familiar with when you wrote your report?

7 A. When I wrote my report? Oh, boy. If it's
8 listed in Exhibit B, then, yes, I would have
9 read it. I would have been knowledgeable
10 about it, but I don't recall specifically.

11 Q. This is something, though, that you got and
12 had the opportunity to specifically review
13 with highlighting on it before your
14 deposition?

15 A. Before today, correct.

16 Q. Yes, sir.

17 A. Yeah.

18 Q. And the highlighting in it is from counsel for
19 Boston Scientific?

20 A. Correct.

21 Q. Is there something of particular significance
22 in this article to you, having reviewed it?

23 MS. GROSSMAN: Object to form.

24 A. Well, to me, it's anoth- -- I've read

1 literally hundreds of articles now on clinical
2 studies, results of clinical studies. This is
3 just another article describing results of a
4 clinical study and I'm a big boy enough to
5 read beyond the highlights.

6 Q. Third article is "Synthetic Biomaterials for
7 Pelvic Floor Reconstruction," from the journal
8 Current Urology Reports, 2005, Karlovsky,
9 et al. This has also got some highlighting
10 and some handwriting in it you see.

11 A. Correct.

12 Q. Was that from counsel for Boston Scientific
13 when it was provided to you?

14 A. Well, actually, that article I identified and
15 I -- but the highlighting is of counsel. The
16 handwriting is mine.

17 Q. The fourth article is "Seventeen years'
18 follow-up of the tension-free vaginal tape
19 procedure for female stress urinary
20 incontinence," by Nilsson and others. Appears
21 to be from the International Urogynecology
22 Journal.

23 A. Correct.

24 Q. A journal you're not a subscriber to?

1 A. Correct.

2 Q. Is this one -- this one just has, it looks
3 like, handwriting, no highlighting. Is this
4 the one that you had and reviewed?

5 A. The handwriting is mine, correct.

6 Q. Yeah, the underlines are yours?

7 A. Right.

8 Q. The fifth is the "Position Statement of
9 Mid-Urethral Slings for Stress Urinary
10 Incontinence" (sic) from the American
11 Urogynecology -- Urogynecologic Society.
12 There's highlighting in this one. Was the
13 highlighting by counsel for Boston Scientific?

14 A. Yes.

15 Q. Was that something you were provided recently?

16 A. I requested -- I requested several things;
17 position statements, whatever we could find in
18 the way of long-term/short-term studies with
19 different products. That came with the batch.

20 Q. Then there is a "Position Statement for (sic)
21 Restriction of Surgical Options for Pelvic
22 Floor Disorders," American Urogynecologic
23 Society. The dates on these are -- do you
24 know if that has an issue date?

1 of experience, fair?

2 A. Fair.

3 Q. In that experience, you read journal articles?

4 A. Constantly.

5 Q. You write journal articles?

6 A. Yes.

7 Q. You're familiar with the process of research

8 leading to a journal article which then goes

9 potentially to publication?

10 A. Correct.

11 Q. You've done that yourself?

12 A. Correct.

13 Q. Your CV identifies, I think, over 100 articles

14 of which you are a co-author in some form or

15 fashion.

16 A. At least, correct.

17 Q. And now Exhibit B identifies probably at least

18 200 articles of which some relevance, either

19 clinically or scientifically, to the issues

20 involved in this matter, fair?

21 A. And which helped in forming my opinion,

22 correct.

23 Q. So that's what I wanted to understand. When

24 you say "when helped in forming my opinion,"

1 that happens, but what's been frustrating to
2 people who want to -- want to support that
3 type of theory is that they -- they have a
4 difficult time proving it, because it's --
5 either it's happened to such a small degree
6 that we don't have sensitive enough techniques
7 yet to figure it out or detect it, or it
8 simply doesn't matter.

9 Q. So is it your opinion that it's possible that
10 polypropylene filament in a -- in a mesh
11 implanted in the female pelvis may degrade as
12 a function of oxidative degradation?

13 MS. GROSSMAN: Object to form.

14 A. Well, I'll -- I'll say this: I'll say that
15 oxidative processes occur; they occur in all
16 our tissues, every part of the body, right.
17 So that -- that -- I'm not disputing that that
18 occurs. What I have not seen is any evidence
19 that oxidative processes have -- affect
20 polypropylene in -- in any detectable way. I
21 have not -- simply the evidence is not there.

22 Q. And -- and so when you say affected in any
23 detectable way, what do you mean?

24 A. I -- I have not seen evidence that changes in

1 the mechanical or material properties occur.
 2 I've not seen evidence of degradation
 3 products, which you would expect to occur. I
 4 have not seen evidence of a host response to a
 5 degradative process. It -- it simply doesn't
 6 happen. And I -- I have done -- I've been in
 7 science long enough that you never say never.

8 You know, I'll give you a good example.
 9 The -- you know, the Rocky Mountains are
 10 degrading constantly. You and I are never
 11 going to see the difference, but it's
 12 happening.

13 Q. Well, if -- if the -- if the inventor of
 14 Pinnacle® has stated that in 100 years when
 15 they dig up the graves (sic) of a woman who
 16 had a -- a Pinnacle®, the only thing they'll
 17 find is her breast implants and her Pinnacle®
 18 implant, do you agree with that?

19 MS. GROSSMAN: Object to form.

20 A. In 100 years?

21 Q. Yes.

22 A. Unless she had something else done, that's
 23 probably true.

24 Q. Okay. So we can agree that the tissue

1 phase of the host tissue response. We've
2 talked about it in terms of injury. It's a
3 similar process, correct, to a foreign body
4 implant?

5 A. Right. Acute refers to the time.

6 Q. Time period?

7 A. Time period, right.

8 Q. But the -- but the pathophysiology specific to
9 the acute period involves a -- specific types
10 of cells, a specific type of response, fair?

11 A. Fair.

12 Q. There is a phase, then, after that that
13 involves a different type of cells, different
14 type of proteins, a different type of
15 response, fair?

16 A. Fair.

17 Q. And then there is a response of the host
18 tissues that can be described to a
19 polypropylene mesh implant as chronic, fair?

20 A. Fair.

21 Q. One of the things that is consistent with a
22 chronic inflammatory response to a
23 polypropylene implant, for example, is
24 something called giant cell macrophages or

1 giant cell foreign bodies?

2 A. Right. They're called multinucleated giant
3 cells. They're -- they're the sine qua non of
4 a foreign body response.

5 Q. It is your opinion that those processes from
6 an acute to subacute, a chronic tissue
7 response to a polypropylene mesh, are
8 predictable?

9 A. Yes.

10 Q. You describe in your report the concept of
11 cell infiltration and collagen deposition
12 (sic) to create the -- the -- the -- I think
13 you describe it as a neotissue around these
14 implants. Is that accurate?

15 A. It is accurate.

16 Q. Is the end result, after that process, in the
17 female pelvis to the implantation of
18 polypropylene mesh, in your opinion, a dense
19 fibrous scar tissue associated with low grade
20 chronic inflammation adjacent to the fibers of
21 the mesh? I'm reading from page 9.

22 A. Is it -- is that -- let's see. Where are you?

23 Q. Page 9.

24 A. The end result, last paragraph?

1 A. I don't know for sure, but it wouldn't
2 surprise me.

3 Q. Would it surprise you if none are used?

4 MS. GROSSMAN: Object to form.

5 A. No.

6 Q. You mention the Material Safety Data Sheet in
7 your report, which I want to mark as Exhibit
8 19.

9 (WHEREUPON, Plaintiffs' Deposition
10 Exhibit Number 19 was marked for
11 identification.)

12 MS. GROSSMAN: Thank you.

13 BY MR. PERDUE:

14 Q. Are you generally familiar with Material
15 Safety Data Sheets from -- from your work?

16 A. Yes, we generate them from my -- my
17 laboratory.

18 Q. Right. I mean, you handle chemicals that are
19 subject to Material Safety Data Sheet when
20 they're passed along -- something comes to
21 your -- stored in something, you get these,
22 right?

23 A. Every day.

24 Q. This one, as you can see, is dated August 3,

1 2001. Do you see that?

2 A. I do.

3 Q. And you reference this in your report. It's
4 actually the first page. You see, "Product
5 Use: MEDICAL APPLICATION CAUTION: Do not use
6 this Chevron Phillips chemical material in
7 medical applications involving permanent
8 implantation in the human body or permanent
9 contact with internal body fluids or tissues."

10 Did I read that correctly? First
11 paragraph under "Product Use."

12 A. Yes.

13 Q. Like we said, you're familiar with these
14 documents in the course of your practice,
15 having a laboratory?

16 A. Yes.

17 Q. From this sheet, given the questions I was
18 asking you earlier, I take it that you cannot
19 determine and you can -- and we can agree, you
20 don't know specifically of whether there is or
21 is not additives, such as antioxidants, in the
22 Marlex® used by Boston Scientific?

23 A. That's correct.

24 Q. This statement, according to this MSDS sheet,